

Directions for use

pH probe calibration and insertion in a Flexel® Bag for LevMixer® | Magnetic Mixer

According to the mixing technology used, please refer to the relevant manual:

- Flexel® for Magnetic Mixer 50L | 100L | 200L | 400L | 650L | 1000L (Ref. 85032-537-50)
- Flexel® Pallettank® for LevMixer® 50L | 100L | 200L | 400L | 650L | 1000L (Ref. 85037-541-12)

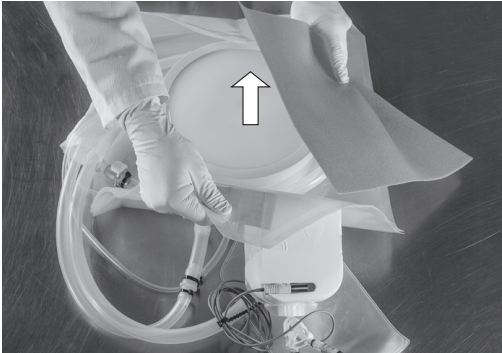
If the Flexel® Bag for LevMixer® | Magnetic Mixer is also equipped with a conductivity device, please also refer to the directions for use "Conductivity probe used in a Flexel® Bag for LevMixer® | Magnetic Mixer" (Ref. IU114256).

Warning:
Please stack horizontally and not more than the required number allowed.
Before pH probe calibration, Good Laboratory Practices (GLP) recommends to place the pH probe and the standard pH solutions at the process temperature.

1. On a flat surface, position the Flexel® Bag for LevMixer® | Magnetic Mixer in such a way that the 8" protective cap is uppermost and the pH probe is in front of you.

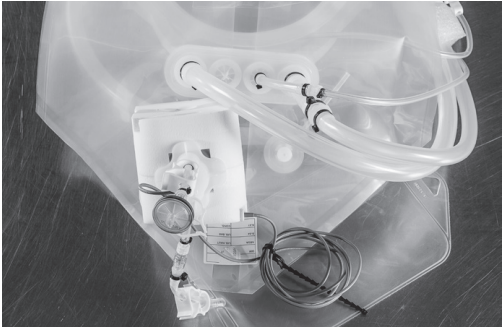


2. Open the flap on the side of the pH probe by removing the tape.

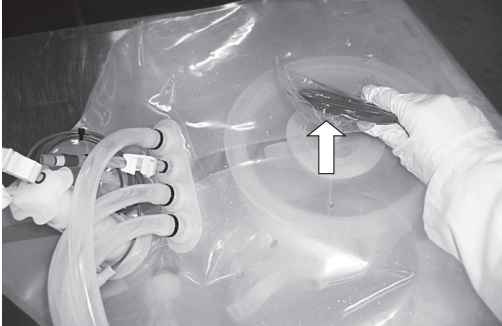


3. Flexel® Bag for LevMixer® | Magnetic Mixer preparation for pH probe calibration

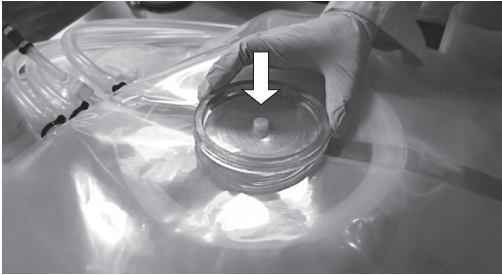
3.1 Flip over the Flexel® Bag for LevMixer® | Magnetic Mixer in such a way that the protective shield (red component) is uppermost and the pH probe is facing you.



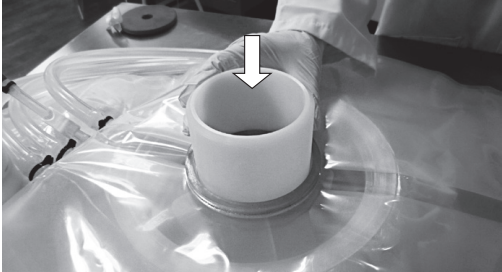
3.2 Remove the red protective shield (there is no need to remove its pouch).



3.3 Position the centering aligner in the dedicated fitting on the Flexel® Bag for LevMixer® | Magnetic Mixer.



3.4 Install the magnetic clamp onto the centering aligner.

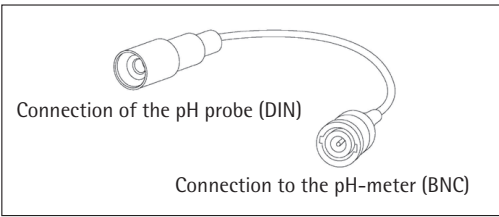


Warning:
Failing to correctly install the centering aligner and magnetic clamp may result in a Flexel® Bag for LevMixer® | Magnetic Mixer damage during filling operations.

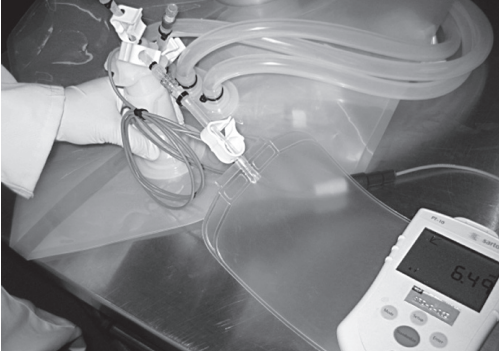
4. Remove the protective foam from the pH probe.



5. Connect the cable of the pH probe (DIN plug) to the pH-meter.
To connect the cable of the pH probe to a Sartorius portable pH-meter (PT-10 or PT-15), a DIN to BNC adapter (Reference FMA114320) is required.



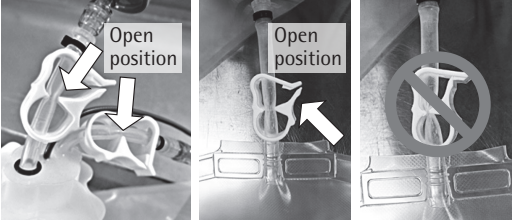
6. Check the functionality of the pH electrode.
An initial pH value of 6.5 ± 0.3 (at room temperature) is indicative of a functional electrode.



If the pH value is not stable, gently shake the probe to remove possible residual air bubbles stuck onto the electrode.
If the pH value is still not correct, flush the storage chamber with one calibration solution.

7. Verifications before calibration

7.1 Make sure that the 2 pinch clamps of the silicone tubing and the pinch clamp of the waste bag are open.



Note:
Even if some crystals or liquid appear inside the tubes or in the flush bag, the pH sensor remains functional if the initial value is 6.5 ± 0.3 (at room temperature).

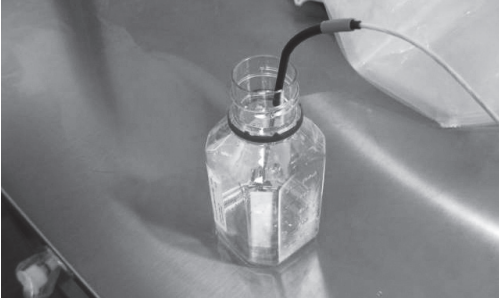
7.2 Make sure that the waste bag is supported on a table without sharp edges.



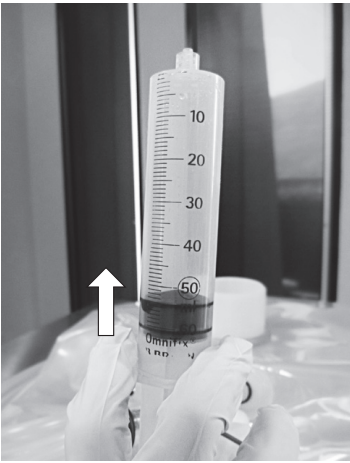
Warning:
Failing to check point 7.1 may result in a leakage of the standard solution into the Flexel® bag for LevMixer® | Magnetic Mixer.

8. pH probe calibration :

8.1 Set the temperature of the first standard pH solution into the pH-meter using a 3 mm OD temperature probe that will be later inserted in the thermowell of the Flexel® Bag for LevMixer® | Magnetic Mixer. The temperature acquisition in the pH-meter can be performed automatically or manually (refer to the User Manual of the pH-meter for detailed instructions).

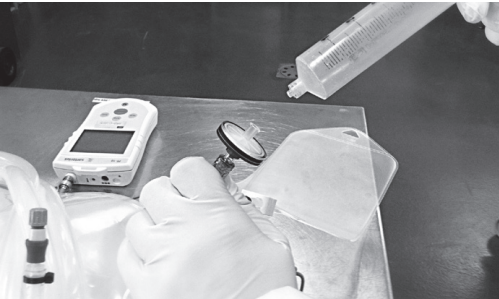


8.2 Fill a 60 mL Luer® syringe with the first standard pH solution. Remove any air residual by slightly pressing the syringe.



Warning:
Failing to remove air from the syringe may result in the impossibility to flush the electrode.

8.3 Connect the filled 60 mL Luer® syringe to the blue 25 mm diameter Minisart® filter (inlet of the probe's chamber).



8.4 First point calibration (refer to the User Manual of the pH-meter for detailed instructions).

Warning:
For the first point calibration, hold the pH probe in a vertical orientation (Minisart® filter and inlet of the Flexboy® Bag at the top) at the rinsing of the 30 first milliliters. Air initially trapped into the storage chamber is removed.



Flush the probe with a **minimum of 120 mL** of the first standard pH solution.

If the pH value is not stable, gently shake the probe to remove possible residual air bubbles stuck onto the electrode.

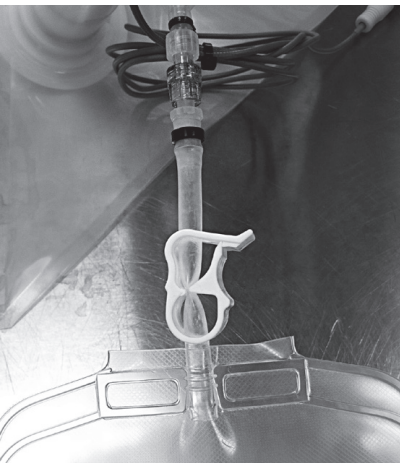
8.5 Second point calibration.
Repeat the above operations (8.4) to calibrate the probe with the second standard pH solution.

8.6 Calibration evaluation.
The pH-meter automatically evaluates the calibration. Refer to the User Manual of the pH-meter to check if the calibration evaluation is within the range of the acceptance criteria.

9. Rinsing of the pH probe's chamber.
Rinse the pH probe with a minimum of 120 mL of WFI (Water For Injection) before insertion of the pH electrode into the Flexel® Bag for LevMixer® | Magnetic Mixer to remove the standard pH solutions.



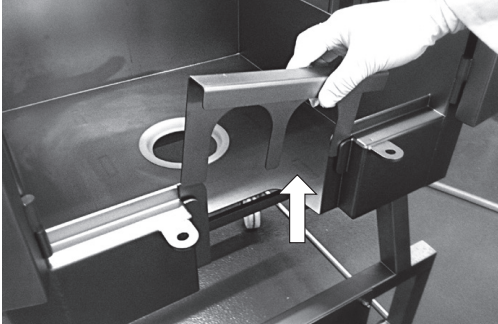
10. Close the 2 pinch clamps of the silicone tubing and the pinch clamp of the waste bag.



11. Open the door of the Pallettank® and check that it is free from particles.



Remove the sliding gate.



12. Flip over the Flexel® Bag for LevMixer® | Magnetic Mixer in order to get the 8" protective cap at the top and the pH probe facing you.



Possibly: Disconnect the pH-meter to facilitate the handling of Flexel® Bag for LevMixer® | Magnetic Mixer.

Warning:
Do not disconnect the waste bag in the case a 2nd calibration is further required by an aseptic process

Hold the Flexel® Bag for LevMixer® | Magnetic Mixer with both arms in such a way that the waste bag is supported.

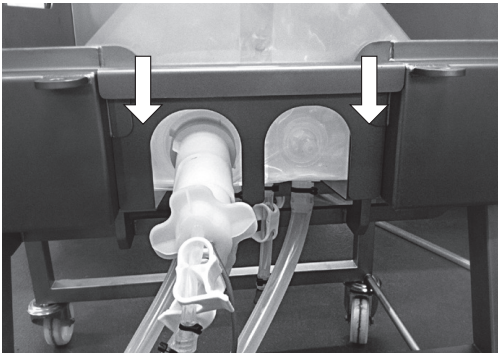


13. Insert the Flexel® Bag for LevMixer® | Magnetic Mixer as per the below picture (refer to the User Manual ref. 85034-536-18 for detailed instructions).



14. Insert the sliding gate.

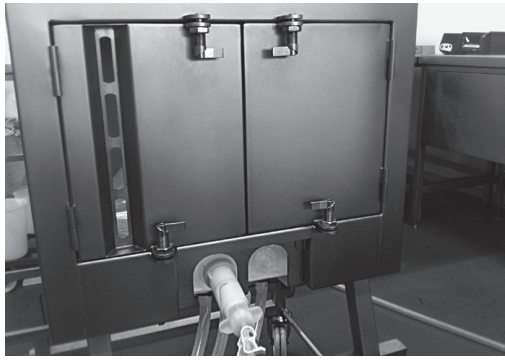
Before inserting the pH sensor into the Flexel® Bag for LevMixer® | Magnetic Mixer, make sure that the sliding gate is well installed.



Close the Pallettank® door.

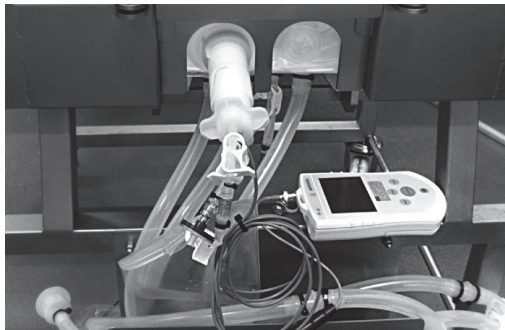
Do not insert a temperature probe into the thermowell of a dry bag. The thermowell must be fully immersed to fit the temperature probe.

Warning:
Fitting a temperature probe in the thermowell of a dry Flexel® Bag for LevMixer® | Magnetic Mixer may result in a damage of the thermowell that results in a leak.

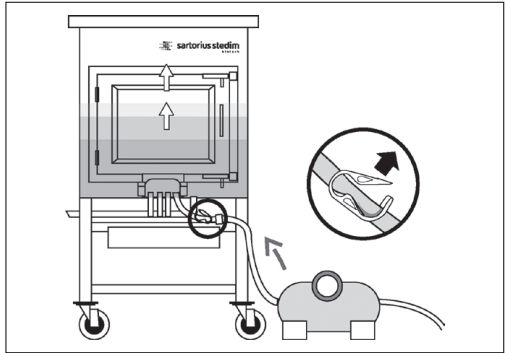


⚠ Warning:
The absence of sliding gate on a Palletank® used with a filled Flexel® Bag for LevMixer® | Magnetic Mixer with pH sensor may result in a bag's exposure with a possible damage of the bag.

⚠ Warning:
Check that the waste bag is well supported by the tubing holder.



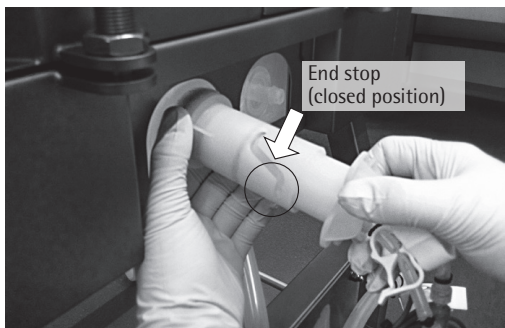
15. Start filling the mixing bag (refer to the User Manual ref. 85034-536-18 for detailed instructions).



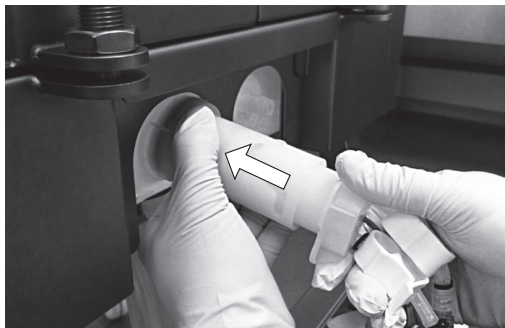
16. pH Probe insertion into the Flexel® Bag for LevMixer® | Magnetic Mixer.

⚠ Warning:
Check that the two pinch clamps on the silicone tubing and the pinch clamp of the waste bag are closed.

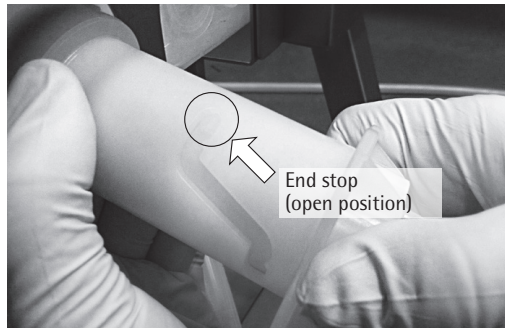
Hold the pH probe device with both hands:
– One on the pH probe main body (static part)
– The other on the pH probe holder (mobile part)



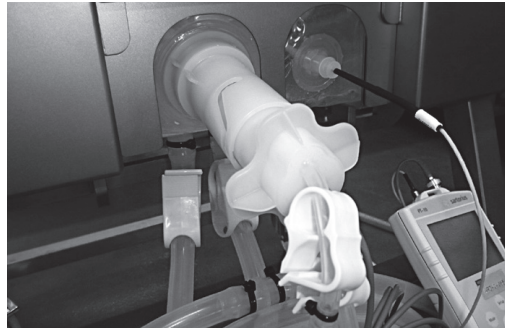
Turn (clockwise) and push the pH probe holder (mobile part) into the pH main body until the end.



17. Check that the pH probe is fully inserted into Flexel® Bag for LevMixer® | Magnetic Mixer.



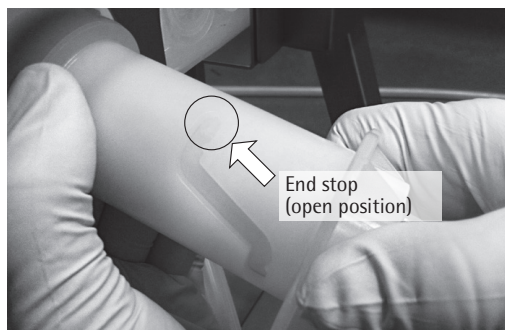
18. Set the temperature from the Flexel® Bag for LevMixer® | Magnetic Mixer by inserting a 3 mm OD temperature probe into the 3 mm ID thermowell.
The temperature acquisition in the pH-meter can be performed automatically or manually (refer to the User Manual of the pH-meter for detailed instructions).



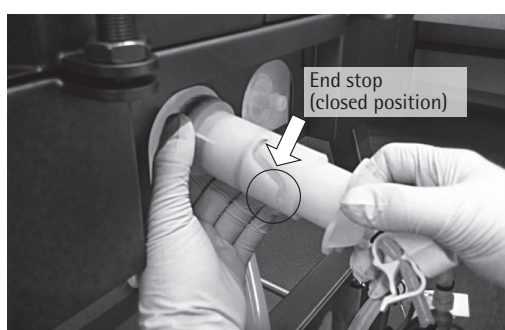
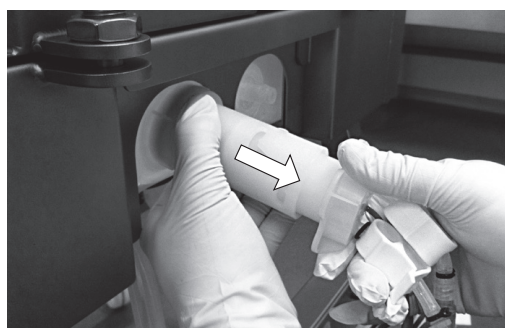
⚠ Warning:
Make sure that the thermowell is fully immersed before fitting the temperature probe.
Fitting the temperature probe in the thermowell of a dry bag may result in a damage of the thermowell that results in a leak.

19. pH probe recalibration

19.1 Hold the pH probe device with both hands:
– One on the pH probe main body (static part)
– The other on the pH probe holder (mobile part)

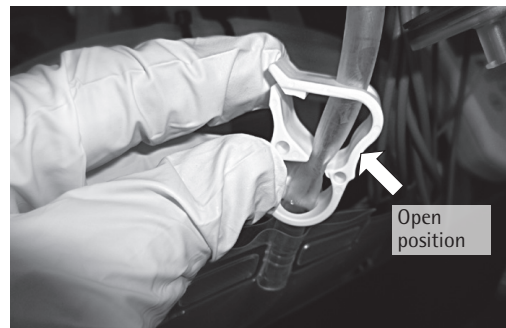
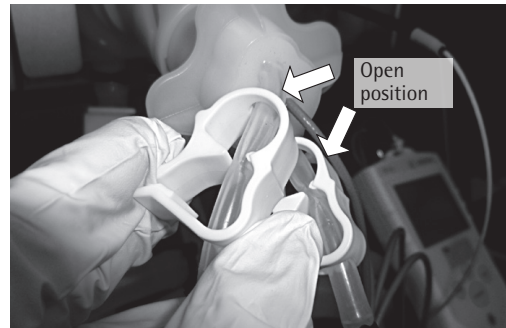


Turn (anti-clockwise) and pull the pH probe holder (mobile part) out of the pH main body.



Check that the pH probe is fully "in closed position" (see picture above)

19.2 Open the 2 pinch clamps of the silicone tubing and the pinch clamp of the waste bag.



19.3 pH probe 2nd calibration

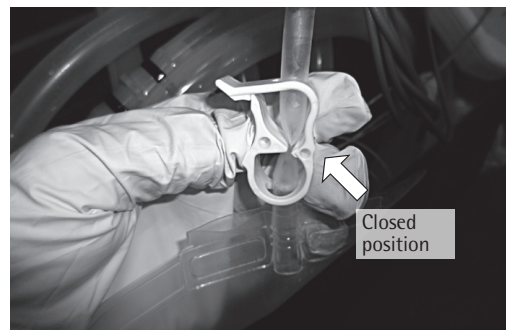
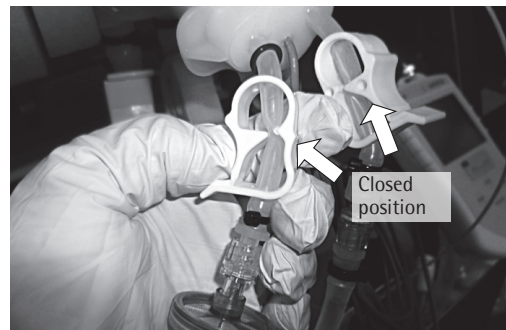
⚠ Warning:
Check that the two pinch clamps on the silicone tubing and the pinch clamp of the waste bag are opened.

Repeat the above operations (8) to recalibrate the pH probe.

19.4 Rinsing of the pH probe chamber.

At the end of calibration process, rinse the pH probe with 120 mL of WFI (Water For Injection) before insertion of the pH electrode into the Flexel® Bag for LevMixer® | Magnetic Mixer.

19.5 Close the 2 pinch clamps of the silicone tubing and the pinch clamp of the waste bag.



19.6 pH probe re-insertion

⚠ Warning:
Check that the two pinch clamps on the silicone tubing and the pinch clamp of the waste bag are closed.

Repeat the above operations (16) to re-insert the pH probe into Flexel® Bag for LevMixer® | Magnetic Mixer.

19.7 Check that the pH probe is fully inserted into Flexel® Bag for LevMixer® | Magnetic Mixer.

⚠ Warning:
The injected pH probe is designed to enable 3 activations (1: 1st insertion, 2: withdrawal, 3: 2nd insertion) while preserving the sterility into the Flexel® Bag for LevMixer® | Magnetic Mixer.

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